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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,717	05/02/2001	Soren Nielsen	NIELSEN=3B	3818

7590 05/31/2006

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,717	NIELSEN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,20,23,25-30,35,39-42 and 44-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,23,26-30,39-42,46,50 and 53* is/are rejected.

7)☒ Claim(s) *20,25,35,44,45,47-49,51 and 52* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 March 2006 has been entered.

Status of Application, Amendments and/or Claims

The amendment filed 10 March 2006 has been entered in full. Claims 3, 4, 6-19, 21, 22, 24, 31-34, 36-38 and 43 are cancelled. New claims 51-53 are added. Claims 1, 2, 5, 20, 23, 25-30, 35, 39-42, 44-53 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection to claims 1, 2, 5, 23 and 39 under 35 U.S.C. 102(b) as being anticipated by Akamatsu *et al.,* US Patent No. 4,745,099, as set forth at pages 3-4 of

the previous Office Action (12 September 2005), is *withdrawn* in view of the amendment (10 March 2006).

The rejection to claims 1, 26-30, 36, 40-42, 46 and 50 under 35 U.S.C. 103(a) as being unpatentable over Akamatsu *et al.,* US Patent No. 4,745,099 in view of Delgado Hernandez *et al.,* Neuroimmunomodulation 6:187-192, 1999, as set forth at pages 4-5 of the previous Office Action (12 September 2005), is *withdrawn* in view of the amendment (10 March 2006).

The objection to claim 38, as set forth at page 5 of the previous Office Action (12 September 2005), is *withdrawn* in view of the amendment (10 March 2006).

The rejection to claims 37 and 38 under 35 U.S.C. 112, first paragraph, written description (new matter), as set forth at page 6 of the previous Office Action (12 September 2005), is *withdrawn* in view of the amendment (10 March 2006).

The objection to claims 28 and 36, as set forth at page 7 of the previous Office Action (12 September 2005), is *withdrawn* in view of the amendment (10 March 2006).

Claim Rejections - 35 USC § 103(a)

Claims 1, 2, 5, 23, 39 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akamatsu *et al.,* US Patent No. 4,745,099 (cited in previous Office Action) in view of Anagnostou *et al.,* US Patent 5,922,674. The instant claims are drawn to a method for treatment or prophylaxis of acute inflammation of the lung or airways, the method comprising administering a therapeutically or prophylactically effective amount of an erythropoietin (EPO) to an individual in need thereof.

Akamatsu *et al.* teach the administration of human EPO for treatment of the anemia of malignant tumors (non-ischemic condition) (abstract, claims). Akamatsu *et al.* teach dosage and timing of EPO administration (column 3, lines 44-52; column 6, lines 30-68 and claims). Akamatsu *et al.* teach the administration of EPO in a Lewis lung carcinoma mouse model (column 6, lines 29-52 and Figures 1 and 2). Akamatsu *et al.* teach the alleviation of anemia in the lung carcinoma mouse models upon administration of EPO (column 6, lines 29-52 and Figures 1 and 2). Lewis lung carcinoma mouse models would exhibit inflammation of the lung or airways. Lung cancer can be caused by smoking (chemical trauma). Akamatsu *et al.* do not specifically teach the administration of EPO for treatment or prophylaxis of acute inflammation of the lung or airways.

Anagnostou *et al.* teach the use of human EPO to treat endothelial injury due to chemotherapy, radiation therapy, **mechanical trauma**, or to **disease states which damage the endothelium**, such as **inflammation**, heart disease or **cancer**)(abstract and column 1, lines 5-15). Anagnostou *et al.* teach a method of treating endothelial injury caused by mechanical damage or inflammation by administering an endothelial-protecting amount of EPO to a subject in need of such treatment (column 2, lines 26-34). Anagnostou *et al.* teach that the use of EPO to enhance endothelial growth and/or repair will be useful to treat disease states adversely affected by the endothelium (column 4, lines 25-40). Anagnostou *et al.* teach dosage and timing of EPO administration (column 6, line 47-column 7, line 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of treating anemia of lung cancer by administering EPO as taught by Akamatsu *et al.* by formulating it to treat acute inflammation of the lungs with a reasonable expectation of success. The motivation and expected success is provided by the fact that the lungs are lined with endothelial cells and Anagnostou *et al.*, who teach the use of human EPO to treat endothelial injury due to mechanical trauma, or to disease states which damage the endothelium, such as inflammation or cancer.

Claim Rejections - 35 USC § 103(a)

Claims 26-30, 40-42, 46 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akamatsu *et al.,* US Patent No. 4,745,099 and Anagnostou *et al.,* US Patent 5,922,674 as applied to claims 1 and 39 above, and further in view of Delgado Hernandez *et al.,* Neuroimmunomodulation 6:187-192, 1999 (cited in the previous Office Action).

The instant claims are drawn to a method for treatment or prophylaxis of acute inflammation of the lung or airways, the method comprising administering a therapeutically or prophylactically effective amount of an erythropoietin (EPO) to an individual in need thereof, further comprising administration of an anti-inflammatory amount of alpha-MSH. The teachings of Akamatsu *et al.* and Anagnostou *et al.* are

described above. Neither reference teaches the administration of alpha-MSH to treat acute inflammation of the lung or airways.

Delgado Hernandez *et al.* teach that administering endotoxin to mice induces endotoxemia (characterized by inflammation of the lung or airways) and increases circulating TNF alpha and nitric oxide (NO). Delgado Hernandez *et al.* teach that administration of alpha-MSH significantly modulated TNF alpha and NO increases in the lung and liver. Delgado Hernandez *et al.* teach that lung myeloperoxidase, a marker of neutrophil infiltration was enhanced by LPS injection (characterized by inflammation of the lung or airways) and was reduced by administration of alpha-MSH (page 189, results and page 191, 1st and 4th paragraph). Delgado Hernandez *et al.* teach the anti-inflammatory activity of alpha-MSH.

The alpha-MSH protein employed by Delgado Hernandez *et al.* is full length and thus comprises the sequences Lys-Pro-Val; Gly-Lys-Pro-Val; His-Phe-Arg-Trp (applies to instant claims 28-30, 41, 42 and 46). Instant claim 50 which, recites the limitation, "wherein said peptide is a fragment, at least three amino acids long, of alpha-MSH" is included in the rejection because the instant claim does not specify the length of the fragment.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Akamatsu *et al.,* Anagnostou *et al.* and Delgado Hernandez *et al.* to make the instant invention of a method for treatment or prophylaxis of acute inflammation of the lung or airways, comprising administering a therapeutically or prophylactically effective amount of an erythropoietin (EPO) to an

individual in need thereof, further comprising administering an anti-inflammatory amount of alpha-MSH. The motivation and expected success is provided by Akamatsu, Anagnostou and Delgado Hernandez. Akamatsu *et al.* teach the administration of EPO to lung cancer mouse models. A lung cancer mice model would have inflammation of the lungs. Anagnostou *et al.* teach the use of human EPO to treat endothelial injury due to mechanical trauma or to disease states that damage the endothelium, such as inflammation or cancer. The lungs are lined with endothelial cells. Delgado Hernandez *et al.* teach the anti-inflammatory activity of alpha-MSH in a lung inflammation mouse model.

Because the inventors teach the efficacy of treatment of inflammation upon administering alpha-MSH or EPO, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in

cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

Claim Objections

Claims 20, 25, 35, 44, 45, 47-49, 51 and 52 are objected to because they depend from a rejected claim.

Conclusion

Claims 1, 2, 5, 23, 26-30, 39-42, 46, 50 and 53 are rejected.

Claims 20, 25, 35, 44, 45, 47-49, 51 and 52 are objected to.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RMD
5/25/06

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